20

25

30

## CLAIMS

138

- A method for preventing or treating cognitive dysfunction in a subject in need thereof, wherein the method comprises treating the subject with a therapeutically effective amount of an aldosterone receptor antagonist or pharmaceutically-acceptable salts thereof.
  - 2. The method of Claim 1 wherein the cognitive dysfunction is selected from the group consisting of psychosis, cognitive disorder, mood disorder, anxiety disorder and personality disorder.
    - 3. The method of Claim 2 wherein the cognitive dysfunction is psychosis characterized by one or more symptoms selected from the group consisting of impairment of behavior, inability to think coherently, inability to comprehend reality, false belief, and abnormal sensations.
  - 4. \_\_\_\_ The method of Claim 2 wherein the cognitive dysfunction is cognitive disorder characterized by one or more symptoms selected from the group consisting of confusion, disorientation, memory disturbance, and behavioral disorganization.
  - 5. The method of Claim 2 wherein the cognitive dysfunction is mood disorder characterized by one or more symptoms selected from the group consisting of depression, bipolar disorder, persistent abnormality of mood, altered activity rhythm, altered sleep, and altered appetite.
  - 6. The method of Claim 2 wherein the cognitive dysfunction is anxiety disorder characterized by one or more symptoms selected from the group consisting of anxiety, panic, dysphoria, obsession, irrational fear, ritualistic behavior, compulsion, and pattern behavior.

- 7. The method of Claim 1 wherein the subject suffers from or is susceptible to one or more conditions selected from the group of conditions consisting of heart disease, kidney disease, stroke, and vascular disease.
- 5 8. A method for improving quality of life in an individual in need thereof, wherein the method comprises administering to the individual a therapeutically effective amount of an aldosterone receptor antagonist, and wherein the treatment results in an improvement in quality of life.
- The method of Claim 8 wherein the improvement in quality of life is assessed using one or more methods selected from the group of methods consisting of HRQOL assessment, SF-36 Health Survey, Kansas City Cardiomyopathy Questionnaire, SF-12 Health Survey, EuroQoL Health Rating Scale, Medical Outcomes Study Depression Scale and Brief Symptom Inventory-Anxiety.

The method of Claim 9 wherein the assessment method is HRQOL assessment.

- The method of Claim 9 wherein the assessment method is SF-36Health Survey.
  - 12. The method of Claim 9 wherein the assessment method is Kansas City Cardiomyopathy Questionnaire.
- 25 13. The method of Claim 9 wherein the assessment method is SF-12 Health Survey.
  - 14. The method of Claim 9 wherein the assessment method is EuroQoL Health Rating Scale.

20

- 15. The method of Claim 9 wherein the assessment method is Medical Outcomes Study Depression Scale.
- 16. The method of Claim 9 wherein the assessment method is Brief5 Symptom Inventory-Anxiety.
  - 17. The method of Claim 8 wherein the individual suffers from or is susceptible to one or more conditions selected from the group of conditions consisting of heart disease, kidney disease, stroke and vascular disease.
  - 18. The method of Claim 1 wherein the aldosterone receptor antagonist is a spirolactone-type compound.
- The method of claim 1 wherein the spirolactone-type compound is selected from the group consisting of:

 $7\alpha$ -acetylthio-3-oxo-4,15-androstadiene-[17( $\beta$ -1')-spiro-5']perhydrofuran-2'-one;

3-oxo-7 $\alpha$ -propionylthio-4,15-androstadiene-[17(( $\beta$ -1')-spiro-

5']perhydrofuran-2'-one;

 $6\beta$ ,  $7\beta$ -methylene-3-oxo4, 15-androstadiene-[17(( $\beta$ -1')-spiro-

5']perhydrofuran-2'-one;

 $15\alpha$ ,  $16\alpha$ -methylene-3-oxo-4,  $7\alpha$ -propionylthio-4-androstene [17(β-1')-spiro-

5']perhydrofuran-2'-one;

 $6\beta, 7\beta, 15\alpha, 16\alpha - dimethylene - 3 - oxo - 4 - and rostene [17(\beta-1') - spiro - 5'] -$ 

25 perhydrofuran-2'-one;

 $7\alpha$ -acetylthio-15 $\beta$ ,16 $\beta$ -Methylene-3-oxo-4-androstene-[17( $\beta$ -1')-spiro-5']perhydrofuran-2'-one;

 $15\beta, 16\beta\text{-methylene-3-oxo-7}\beta\text{-propionylthio-4-androstene-}[17(\beta\text{-1'})\text{-spiro-5'}] perhydrofuran-2'-one; and$ 

- $6\beta,7\beta,15\beta,16\beta$  -dimethylene-3-oxo-4-androstene-[17( $\beta$ -1')-spiro-5']perhydrofuran-2'-one.
- 20. The method of Claim 1 wherein the aldosterone receptor antagonist is spironolactone.
  - 21. The method of Claim 1 wherein the aldosterone receptor antagonist is an epoxy-steroidal aldosterone antagonist.
- 10 22. The method of Claim 21 wherein the epoxy-steroidal compound has an epoxy moiety fused to the "C" ring of the steroidal nucleus of a 20-spiroxane compound.
- 23. The method of Claim 21 wherein the 20-spiroxane compound is characterized by the presence of a 9-alpha,11-beta-substituted epoxy moiety.
  - 24. The method of Claim 1 wherein the aldosterone receptor antagonist is epoxymexrenone.
- 20 25. The method of Claim 1 wherein the aldosterone receptor antagonist is drospirenone.
  - 26. The method of Claim 21 wherein the amount of epoxy-steroidal compound administered is between about 0.25 mg to about 400 mg per day
  - 27. The method of Claim 21 wherein the therapeutically-effective amount of epoxy-steroidal compound administered is between about 5 mg to about 200 mg per day.
- 30 28. The method of Claim 21 wherein the therapeutically-effective amount of epoxy-steroidal compound administered is between about 25 mg to about

10

20

100 mg per day.

- 29. The method of Claim 21 wherein the therapeutically-effective amount of epoxy-steroidal compound administered is between about 10 mg to about 15 mg per day.
- 30. The method of Claim 8 wherein the aldosterone receptor antagonist is a spirolactone-type compound.
- 31. The method of claim 8 wherein the spirolactone-type compound is selected from the group consisting of:

 $\label{eq:condition} 7\alpha\text{-acetylthio-3-oxo-4,15-androstadiene-[17(\beta\text{-1'})\text{-spiro-5'}]perhydrofuran-2'-one;}$ 

3-oxo-7 $\alpha$ -propionylthio-4,15-androstadiene-[17(( $\beta$ -1')-spiro-

15 5']perhydrofuran-2'-one;

 $6\beta$ , 7 $\beta$ -methylene-3-oxo4, 15-androstadiene-[17(( $\beta$ -1')-spiro-

5']perhydrofuran-2'-one;

 $15\alpha$ ,  $16\alpha$ -methylene-3-oxo-4,  $7\alpha$ -propionylthio-4-androstene [17( $\beta$ -1')-spiro-5'] perhydrofuran-2'-one;

 $6\beta,7\beta,15\alpha,16\alpha\text{-dimethylene-3-oxo-4-androstene} [17(\beta\text{-}1')\text{-spiro-5'}]$  perhydrofuran-2'-one;

 $7\alpha\text{-acetylthio-15}\beta,16\beta\text{-Methylene-3-oxo-4-androstene-[17(\beta-1')\text{-spiro-5']perhydrofuran-2'-one;}}$ 

 $15\beta, 16\beta\text{-methylene-3-oxo-7}\beta\text{-propionylthio-4-androstene-} [17(\beta\text{-1'})\text{-spiro-1}]$ 

25 5']perhydrofuran-2'-one; and

 $6\beta,7\beta,15\beta,16\beta\text{-dimethylene-3-oxo-4-androstene-}[17(\beta\text{-}1')\text{-spiro-5']perhydrofuran-2'-one.}$ 

32. The method of Claim 8 wherein the aldosterone receptor antagonist is spironolactone.

15

20

- 33. The method of Claim 8 wherein the aldosterone receptor antagonist is an epoxy-steroidal aldosterone antagonist.
- 5 34. The method of Claim 33 wherein the epoxy-steroidal compound has an epoxy moiety fused to the "C" ring of the steroidal nucleus of a 20-spiroxane compound.
  - 35. The method of Claim 33 wherein the 20-spiroxane compound is characterized by the presence of a 9-alpha,11-beta-substituted epoxy moiety.
  - 36. The method of Claim 8 wherein the aldosterone receptor antagonist is epoxymexrenone.
  - 37. The method of Claim 8 wherein the aldosterone receptor antagonist is drospirenone.
  - 38. The method of Claim 33 wherein the amount of epoxy-steroidal compound administered is between about 0.25 mg to about 400 mg per day

39. The method of Claim 33 wherein the therapeutically-effective amount of epoxy-steroidal compound administered is between about 5 mg to about 200 mg per day.

- 25 40. The method of Claim 33 wherein the therapeutically-effective amount of epoxy-steroidal compound administered is between about 25 mg to about 100 mg per day.
- 41. The method of Claim 33 wherein the therapeutically-effective
  30 amount of epoxy-steroidal compound administered is between about 10 mg to about
  15 mg per day.